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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MANFRED BROCKHAUS, ZLATKO DEMBIC,
REINER GENTZ, WERNER LESSLAUER, HANSRUEDI LOTSCHER,
and ERNST-JURGEN SCHLAEGER

Appeal 2009-014889
Application 08/444,790
Technology Center 1600

Before CAROL A. SPIEGEL, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for failing to comply with the written description requirement and as obvious over the applied prior art. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF CASE

The following claim is representative.

62. A protein comprising

(a) a human tumor necrosis factor (TNF)-binding soluble fragment of an insoluble human TNF receptor, wherein the insoluble human TNF receptor (i) specifically binds human TNF, (ii) has an apparent molecular weight of about 75 kilodaltons on a non-reducing SDS-polyacrylamide gel, and (iii) comprises the amino acid sequence LPAQVAFXPYAPEPGSTC (SEQ ID NO: 10); and

(b) all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain of said constant region;

wherein said protein specifically binds human TNF.

Cited References

Smith et al.	US 5,395,760	Mar. 7, 1995
Capon et al.	US 5,116,964	May 26, 1992

Smith et al., *A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins*, 248 SCIENCE 1019-1023 (1990).

Dembic et al., *Two Human TNF Receptors Have Similar Extracellular, but Distinct Intracellular, Domain Sequences*, 2 CYTOKINE 231-237 (1990).

Chan et al., *A Domain in TNF Receptors That Mediates Ligand-Independent Receptor Assembly and Signaling*, 288 SCIENCE 2351-2354 (2000).

Grounds of Rejection

1. Claims 62, 102, 103, 105-107, 110, 111, 113, 114, 119-121 and 123-137 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

2. Claims 62, 102, 103, 105-107, 110, 111, 113, 114, 119-121, 125-131 and 134-137 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dembic et al. in view of Capon et al.

3. Claims 140-144 are rejected under 35 U.S.C. § 112, first paragraph, as introducing new matter.

Discussion

1. Claims 62, 102, 103, 105-107, 110, 111, 113, 114, 119-121 and 123-137 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

ISSUE

The Examiner concludes that the claims encompass a genus of soluble TNF which is not supported by a sufficient representative number of species. (Ans. 17.)

Appellants argue that the claims encompass soluble TNF binding fusion proteins and that when the claims are read in view of the state of the art the disclosure supports the scope of proteins claimed.

The issue is: Does the written description support the pending claims' scope?

PRINCIPLES OF LAW

> The "written description" requirement . . . serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. . . .
>
> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

> Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Id. at 1359.

Where "accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences . . . , satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006) (footnote omitted).

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). In order to determine whether a prima facie case of obviousness has been established, we consider the factors set forth in

Graham v. John Deere Co., 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

The deposit requirement doesn't need to be satisfied as of filing date. *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985).

ANALYSIS

Appellants argue that "the Examiner's requirement that the specification reiterate sequences known in the prior art is contrary to controlling precedent in factually parallel cases." (App. Br. 16.) Appellants put forth the Declaration of Lyman[2] in support of the position that the complete gene sequence of the 75Kd TNF binding peptide was known in the art at the time of filing of the instant Specification. Appellants argue that the claims encompass soluble TNF binding fusion proteins and that when the claims are read in view of the state of the art the disclosure supports the scope of the proteins claimed.

We agree with Appellants that the record supports the fact that the art was aware of the entire gene sequence of the 75Kd TNF binding peptide. Thus, when the written description is read in view of the state of the art, we find that the written description supports the pending claim scope.

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[2] Declaration of Stewart Lyman, Ph.D, submitted August 6, 2007.

CONCLUSION OF LAW

The written description supports the pending claim scope and thus the written description rejection is reversed.

2. Claims 62, 102, 103, 105-107, 110, 111, 113, 114, 119-121, 125-131 and 134- 137 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dembic et al in view of Capon et al.

ISSUE

The Examiner argues that

> It would have been obvious to the person of ordinary skill in the art at the time the invention was made to fuse the extracellular portion of the 75 kD human TNF receptor sequence taught by Dembic to the Fc region taught by Capon, and to recombinantly produce the protein in CHO cells and purify the protein produced as taught by Capon. The person of ordinary skill in the art would be motivated to do so in order to produce and purify the TNF receptor-1g fusion for use in affinity purification of the TNF ligand. The person of ordinary skill in the art would have expected success because Capon teaches that lg fusions can be made with a wide variety of proteins, and teaches all of the techniques for recombinant production of hybrid immunoglobulins in CHO cells and purification of the produced protein.

(Ans. 19-20.)

Appellants contend that "the rejection should be reversed because the Examiner's refusal to evaluate Appellants' overwhelming evidence of unexpected results is contrary to controlling case law and Appellants' evidence of unexpected results rebuts any possible case of obviousness." (App. Br. 39.)

The issue: Is Appellants' evidence of unexpected results convincing to rebut the Examiner's obviousness rejection?

ANALYSIS

The Examiner took the position that Appellants' unexpected results appear to be generated using a fusion protein comprising a full length extracellular domain of the insoluble 75 kD TNF binding receptor and portions of an immunoglobulin molecule, however the specification does not provide a written description of this species of fusion protein. (Ans. 61.) The Examiner, further, does not dispute Appellants' unexpected results related to drastically reduced effector function observed for the claimed fusion protein. *Id.* at 63. The claimed fusion protein additionally had excellent binding activity, unexpectedly high kinetic stability, and improved inhibition of the effect of TNF in biological cell culture tests. (Declaration of Lesslauer, Exhibit B.)

We have concluded herein that the written description does support a fusion protein comprising a full length extracellular domain of the insoluble 75 kD TNF binding receptor. This fact, taken with the fact that the Examiner does not dispute Appellants' unexpected results, supports a conclusion of nonobviousness.

CONCLUSION OF LAW

Appellants' evidence of unexpected results is convincing to rebut the Examiner's obviousness rejection. The obviousness rejection is reversed.

3. Claims 140-144 are rejected under 35 U.S.C. § 112, first paragraph, for new matter.

The Examiner finds that Appellants' amendment to the Specification concerning the deposit with the ATCC to be new matter. (Ans. 20-21.)

Appellants argue that the law requires that the description of a deposit must be sufficient to permit verification that the deposited biological material is in fact that disclosed. (App. Br. 63.)

It is well settled that the deposit requirement doesn't need to be satisfied as of filing date. *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985). Appellants amended the Specification on November 14, 2006 to deposit the insoluble and soluble fragments of TNF binding proteins having an apparent molecular weight of 65.75 kD originally described in the Specification. (App. Br. 63.) Appellants put forth the Declaration of Lesslauer[3] as evidence that a person of ordinary skill in the art would recognize that the Specification as filed permits verification that the deposited biological material is in fact that disclosed. (*Id.*) We are persuaded by Appellants' argument.

The Examiner further argues that the deposited material contains more sequence, such as the signal sequence, than that displayed in Fig. 4. (Ans. 73.) Appellants respond by arguing that the signal sequence is not part of the soluble fragment encoded by the deposited construct and that the claims exclude the signal sequence. (App. Br. 64.) Again we are persuaded by Appellants' argument.

The new matter rejection of claims 140-144 is reversed.

REVERSED

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[3] Third Declaration of Dr. Werner Lesslauer, submitted Nov. 9, 2006.

cdc

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